IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

GENZYME CORPORATION, *Plaintiff,* v. LUPIN LTD., et al., *Defendants.*	Civil Case No. JFM-09-563 JFM-09-1258 JFM-10-1906
GENZYME CORPORATION, *Plaintiff,* v. IMPAX LABORATORIES, INC. *Defendant*.	Civil Case No. JFM-09-653 JFM-09-846 JFM-10-1791
GENZYME CORPORATION, *Plaintiff,* v. SANDOZ, INC. *Defendant.*	Civil Case No. JFM-09-1750 JFM-10-1715
GENZYME CORPORATION, *Plaintiff,* v. ENDO PHARMACEUTICALS, INC. *Defendant*.	Civil Case No. JFM-09-2589

MEMORANDUM

Plaintiff Genzyme Corporation ("Genzyme") has filed actions against defendants Endo Pharmaceuticals Inc., Impax Laboratories Inc., Sandoz Inc., Lupin Ltd., and Lupin

Pharmaceuticals Inc. for infringement of United States Patent No. 5,667,775 ("the '775 Patent"). After more than a year of fact discovery, Defendants Impax Laboratories, Inc., Lupin, Ltd., and Lupin Pharmaceuticals, Inc. (collectively, "Defendants") have filed a motion to compel plaintiff Genzyme Corp. ("Genzyme") to: "(1) produce all laboratory notebooks reporting phosphate binding tests of hydrophilic, cross-linked, aliphatic amine polymers and documents sufficient to identify those polymers within ten (10) days; and (2) produce a witness to testify about those documents." (Defs.' Mem. at 2.) Having reviewed Defendants' motion and all related briefings and submissions, I have determined that no hearing is necessary to resolve this dispute. Local Rule 105.6 (D. Md.). For the following reasons, Defendants' motion is denied.

I. BACKGROUND

Plaintiff Genzyme is a drug manufacturer and the holder of the '775 Patent, which relates to the therapeutic use of certain types of molecules, called "amine polymers," to combat hyperphosphatemia, an excess of phosphorous in the body often occurring in individuals with impaired kidney function. Using the technology described in the '775 Patent, Genzyme developed two drugs, RENAGEL® and RENVELA®, to combat chronic kidney disease. Defendants are drug manufacturers seeking to market generic versions of these products. Genzyme alleges that Defendants have infringed its '775 Patent and filed this action in federal court.

Pursuant to a December 1, 2009 Scheduling Order, fact discovery in this case began in February 2010 and was scheduled to close on December 3, 2010. (Scheduling Order, Dec. 1, 2009, ECF No. 64.) Discovery continued throughout 2010, and following a meet and confer in November 2010, the parties reached a "universal agreement to resolve all discovery disputes" that had arisen. (Defs.' Ex. F, Letter of Nov. 22, 2010, at 1.) Under the agreement, Genzyme

consented to produce all "inventor laboratory notebooks dated on or before September 16, 1997," the issuance date of the '775 Patent. (*Id.* at 2.) In return, Impax agreed "not to seek any further document production, with the exception of reasonable and focused requests for documents covered by the document requests served to date." (Defs.' Ex. G, Letter of Nov. 30, 2010, at 2.) Subsequent to this agreement, and upon the consent of the parties, the fact discovery deadline was reset for February 28, 2011, (Am. Scheduling Order, Dec. 3, 2010, ECF No. 78), and later extended again until March 25, 2011 "for the purpose of completing and obtaining discovery served on or before December 3, 2010." (Am. Scheduling Order, Mar. 3, 2011, ECF No. 89.) Expert depositions are scheduled for August 2011, and trial is set to begin in September 2012.

Despite having reached a negotiated discovery agreement, a discovery dispute arose just days before the fact discovery deadline when Defendants requested that Genzyme produce all laboratory notebooks related to phosphate binding tests of certain polymers dated after the issuance of the '775 Patent. (*See* Defs. Exs. I & J, Letters of March 23 and 24, 2011.) Defendants assert that they are entitled to discovery of these notebooks because they could be relevant to a potential lack of enablement defense.[1] Genzyme has refused Defendants' document request on the grounds that it is untimely, contrary to the parties' negotiated discovery agreement, and unduly burdensome. Because I find that Defendants' request is unjustifiably

[1] Defendants assert that if the post-issuance testing showed that one or more of the compounds covered by the '775 Patent were not "effective" in removing phosphate as claimed, then the patent itself would be invalid for the lack of enablement and written description. *See* 35 U.S.C. § 112; *see also Auto. Techs. Int'l Inc. v. BMW of North Am., Inc.*, 501 F.3d 1274, 1285 (Fed. Cir. 2007) ("[I]n order to fulfill the enablement requirement, the specification must enable the full scope of the claims . . . ."). Genzyme disputes this theory and asserts that "[i]t is not necessary that every permutation within a generally operable invention be effective." *Capon v. Eshhar*, 418 F.3d 1349, 1359 (Fed. Cir. 2005). I need not address the merits of this issue in resolving the motion now before me.

delayed and in contravention of the parties' binding discovery agreement, the Motion to Compel is denied.

II. ANALYSIS

Pursuant to Rule 26(b), a court "must limit the frequency or extent of discovery otherwise allowed by these rules or by local rule if it determines that . . . the party seeking discovery has had ample opportunity to obtain the information by discovery in the action." Fed. R. Civ. P. 26(b)(2)(C)(ii). Fact discovery in this case spanned thirteen months, from February 2010 to March 25, 2011, and the discovery deadline already has been twice extended. During this period, Defendants had ample time to request the documents they now seek, but instead they waited until the week of the discovery deadline to make their demand for the post-issuance laboratory notebooks. When evaluating such last-minute requests for additional discovery, a district court properly "declines to extend discovery . . . when [a party] had many months to make both her initial and follow-up discovery requests." *Yoon v. Sebelius*, CBD-08-3173, 2010 WL 2730620, at *1 (D. Md. July 9, 2010). This guidance, which is consistent with the language of Rule 26(b), indicates that Defendants' Motion to Compel should be denied.

Defendants, however, maintain that they are not at fault for any delay in requesting this discovery. Instead, they assert that "to the extent Genzyme contends this motion was in any sense untimely, it has only itself to blame." (Defs.' Reply at 4.) Specifically, Defendants emphasize that Genzyme produced a memorandum on March 21, 2011—the eve of the deposition of Dr. Randall Holmes-Farley, Genzyme's Rule 30(b)(6) designee—that purportedly questions the effectiveness of certain polymers covered by the '775 patent.[2] (Defs.' Mem. at 6-

[2] The memorandum in question was written in 1994 by Dr. Holmes-Farley, a Genzyme employee and named inventor of the '775 patent. In the memorandum, Dr. Holmes-Farley called "ineffective" certain polymers discussed in a patent application submitted by another group of

8.) Defendants assert that this "eleventh-hour disclosure of the memorandum, along with Dr. Holmes-Farley's inconsistent and incomplete testimony" created new questions about the written description and enablement of the '775 Patent and necessitated the last-minute request for additional discovery of post-issuance laboratory notebooks. (*Id.* at 8.) In short, Defendants argue that Genzyme's delay in turning over the Holmes-Farley memorandum prevented them from fully understanding the relevance of the post-issuance laboratory notebooks until mere days before the discovery deadline.

The facts, however, do not support Defendants' version of events. In fact, Defendants first requested additional discovery into the post-issuance laboratory notebooks on March 19, 2011, two days *before* Genzyme's production of the Holmes-Farley memorandum. (*See* Defs. Ex. J, Letter of March 24, 2011 [describing Defendants' request for these documents during teleconferences on March 19 and 20, 2011].) Thus, Defendants could not have known that the memorandum even existed at the time of their request for the post-issuance laboratory notebooks. In this light, their complaints about Genzyme's last-minute production of the memorandum appear to be little more than an attempt to distract the Court from their own delay in requesting the post-issuance notebooks. This type of pretextual justification for permitting further discovery is unpersuasive, as evidenced by a recent opinion authored by one of my colleagues on the District of Maryland:

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inventors. However, he described these same polymers as "effective" when Genzyme tested them several years later after the issuance of the patent. (Defs.' Mem. at 6-8.) When asked about this apparent contradiction during his deposition, Dr. Holmes-Farley stated that when he wrote that the polymers were "ineffective" in 1994, he meant that although they may have bound some amount of phosphate, "they were not effective enough for us to pursue." (Holmes-Farley Dep. at 112-13.) In the context of Genzyme's post-issuance testing, however, Dr. Holmes-Farley explained that the term "ineffective" was used to refer to polymers that did not bind any phosphate.

> Plaintiff argues that [the deponent's] evasive answers during deposition necessitate a second deposition and a discovery period extension. However, Plaintiff's counsel raised the need to extend the deadline with Defendant on June 3, 2010 and reiterated that need on June 17, 2010, well before [the deponent's] deposition on June 28, 2010. When he proposed the extension to Defendant, Plaintiff's counsel could not have known the substance of [the deponent's] deposition. Therefore, using this as a rationale for an extension falls short.

Yoon, 2010 WL 2730620, at *1. Just as in *Yoon*, Defendants' attempt to shift the blame to Genzyme for its belated discovery request is unconvincing.

In addition to Defendants' undue delay, their demand for the post-issuance laboratory notebooks also contravenes the plain language of the parties' negotiated discovery agreement. In November 2010, the parties reached a universal discovery agreement wherein Genzyme agreed to produce all laboratory notebooks created prior to the 1997 issuance of the patent in return for Defendants' promise "not to seek any further document production, with the exception of reasonable and focused requests for documents covered by the document requests served to date." (Defs.' Ex. G at 2.) The parties do not dispute that Genzyme has upheld its pledge to produce all of laboratory notebooks dated on or before the issuance date of the patent, a period of approximately six years. Nonetheless, Defendants now seek laboratory notebooks created *after* the issuance of the patent in 1997. Despite the fact that this request would extend the temporal scope of discovery from six to nineteen years and require Genzyme to produce an untold number of new documents, Defendants argue that it is the kind of "reasonable and focused" request for additional discovery permitted by the negotiated agreement. Defendants are incorrect. A request for a large number of new documents spanning a period of thirteen years is neither "focused" nor "reasonable," especially when it is made just days before the discovery deadline after thirteen

months of delay. Accordingly, the plain language of the parties' discovery agreement also requires the denial of Defendants Motion to Compel.[3]

For the foregoing reasons, Defendants' Motion to Compel is DENIED. A separate order implementing this decision is being entered herewith.

Date: June 21, 2011

/s/
J. Frederick Motz
United States District Judge

[3] In addition to request for the post-issuance laboratory notebooks, Defendants also request that Genzyme produce a witness to testify about those documents. (Defs.' Mem. at 2.) This request for testimony is rendered moot by my holding that Genzyme need not produce the laboratory notebooks.